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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,241	09/05/2007	Peixuan Guo	570024.402USPC	2305

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EXAMINER	
CHONG, KIMBERLY	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,241	GUO ET AL.	
	Examiner	Art Unit	
	KIMBERLY CHONG	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/23/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,17,18 and 28-37* is/are pending in the application.

4a) Of the above claim(s) *17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 28-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 12/23/2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 06/23/2010 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 12/23/2010, claims 1-48 are pending. Claims 1-5, 7, 8, and 28-37 are currently under examination. Claims 17-18 are withdrawn as being drawn to a non-elected invention. Claims 38-48 are cancelled.

New Claim Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-8, and 28-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 7,655,787. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

The instant claims are drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers wherein each pRNA independently comprises a heterologous component, wherein the at least one chimeric pRNA comprises an end-labeling agent and wherein at least one pRNA incorporates at least one nucleotide analog.

Claims 1-17 of U. S. Patent No. 7,655,787 are drawn to a polyvalent complex comprising a pRNA monomers comprising a biologically active RNA and to methods of delivering said biologically active RNA. It would have been obvious to one of skill in the art to use the complex of Patent '787 to make the polyvalent multimeric complex of the instant application and the polyvalent multimeric complex is an obvious variation of the claimed invention. Patent '787 in paragraphs 71 and 72, reproduced below teach an important characteristic of the chimeric molecule and the ability to be used as a multimeric pRNA.

> 71) Importantly, formation of a dimer or a hexamer also facilitates the ability of the chimeric molecule to carry multiple therapeutic agents. A complex of two or more circularly permuted pRNA is termed herein a polyvalent multimeric pRNA. A dimeric complex will contain two spacer regions and hence two biologically active moieties. For example, one of the pRNA subunits of a hexamer could carry the hammerhead ribozyme, and the other pRNA subunit could carry a hairpin ribozyme or an antisense RNA (FIG. 8). Applications of multiple therapeutic agents might enhance the efficiency of the in vivo therapy.

> (72) The polyvalent multimeric pRNA could also be used to specifically target and deliver the therapeutic agent, such as a ribozyme. For example, one of the subunits can be used to carry an RNA aptamer or other molecule (such as an antibody) that interacts with a cell-surface receptor or other component of the cell membrane or cell wall. Binding of the dimer or hexamer pRNA to a specific receptor would, for example, enable the specific delivery of the pRNA complex to the cell via endocytosis.

Further Chen et al. (JBC 2000, Vol. 275, 17510-17516, cited on IDS filed 07/19/2007) teach the circularly permuted pRNAs can form multimeric complexes and thus it would have further been obvious to use the claimed pRNA in Patent '787 in a multimeric complex.

Thus, claims 1-5, 7-8 and 28-37 of the instant application are an obvious variation of claims 1-17 of Patent '787.

Claims 1-5, 7-8 and 28-37 are provisionally rejected under the judicially created doctrine of double patenting over claims 15, 16 and 19-29 of copending Application No. 11/989,590. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent are drawn to patently indistinguishable subject matter.

The instant claims are drawn to a polyvalent multimeric complex comprising a plurality of chimeric pRNA monomers wherein each pRNA independently comprises a heterologous component, wherein the at least one chimeric pRNA comprises an end-labeling agent and wherein at least one pRNA incorporates at least one nucleotide analog.

Claims 15, 16 and 19-29 of the copending Application No. 11/989,590 are drawn to a polyvalent multimeric pRNA complex comprising a siRNA.

Thus the instant claims 1-5, 7-8 and 28-37 and claims 15, 16 and 19-29 of copending Application No. 11/989,590 overlap in scope.

Response to Arguments

Claim Rejections - 35 USC § 112

The rejection of claim 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot as this claim has been canceled.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 5, 28, and 36 under 35 U.S.C. 102(b) as being anticipated by Chen et al. (Journal of Biol. Chem 2000 of record cited on IDS filed 07/19/2007) is withdrawn due to claim amendments.

Claims 1-5, 28-32, and 35-37 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoeprich et al. (Gene Therapy 2003 of record cited on IDS filed 07/19/2007) is withdrawn.

Applicant argues Hoeprich et al. is not prior art because the instant claims have the benefit of prior application 60/433,697. This argument is not correct because the priority application does not disclose a polyvalent multimeric complex comprising a

plurality of pRNA and while the priority application discloses a pRNA monomer comprising a biologically active RNA, the only biologically active RNA disclosed in the priority application is a ribozyme. The instant claims teach the use of a biologically active RNA such as an antisense, a siRNA, a RNA aptamer or a peptide nucleic acid none of which are taught by the priority application. Thus because the limitation "a biologically active RNA" embrace the molecules as discussed above and the priority application 60/433,697 does not teach the breadth of the claimed invention and only disclose the use of a ribozyme, the rejection is maintained.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

If Applicant feels the priority application 60/433,697 does provide support for use of a multimeric complex and a biologically active RNA such as an antisense, a siRNA, a RNA aptamer or a peptide nucleic acid, applicants are requested to point out with particularity to where such support may be found.

Thus, the claims are accorded a priority date of 12/16/2003 the filing date of the priority document PCT/US03/39950.

Claim Rejections - 35 USC § 103

The rejection of claims 1-8, and 28-37 under 35 U.S.C. 103(a) as being unpatentable over Hoeprich et al. (Gene Therapy 2003 of record cited on IDS filed 07/19/2007) and Bennett et al. (US Patent No. 5,998,148) is maintained for the reasons above, specifically because Hoeprich et al. is available as prior art.

In the interest of compact prosecution please note the following: In the event the rejections are overcome against the product claims above, methods of using the product in claims 17 and 18 would be rejoined however these claims would be subject to a 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claims 17 and 18 recites the limitation "a therapeutic agent" as the heterologous component. There is insufficient antecedent basis for this limitation in the claim because claim 1 recites "the heterologous component" as a biologically active RNA and the recitation of a therapeutic agent embraces more than biologically active RNA. Therefore the limitation "a therapeutic agent" does not have antecedent basis in claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact the SPE for 1635 Heather Calamita at 571-272-2876. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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/Kimberly Chong/
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